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| 09/821,244 | 03/29/2001 | J. Guy Breitenbucher | ORT-1395 | 7145 |

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EXAMINER

DENTZ, BERNARD I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1625

DATE MAILED: 08/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,244

Applicant(s)

BREITENBUCHER ET AL.

Examiner

Bernard Dentz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13, 23-26 and 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-22 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,6.
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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A new restriction requirement is made herein per the conversation with Ms. Shen on 8-8-2002.

Restriction is required as follows:

In the first 6 Groups the corresponding pharmaceutical compositions are included.

- I. Compounds where W is OR and Z is heterocyclyl.
- II. Compounds where W is OR and Z is the non-hetero value.
- III. Compounds where W is R_9 and Z is heterocyclyl.
- IV. Compounds where W is R_9 and Z is the non-hetero value.
- V. Compounds where W is the other values and Z is heterocyclyl.
- VI. Compounds where W is the other values and Z is the non-hetero value.

Non-hetero value refers to $NR_{11}R_{12}$.

In the next 6 Groups "methods" refers to specific pharmaceutical methods of treatment using the compounds.

- VII. Methods wherein W is OR and Z is heterocyclyl
- VIII. Methods where W is OR and Z is the non-hetero value
- IX. Methods where W is R_9 and Z is the non-hetero value
- X. Methods where W is R_9 and Z is the non-hetero value
- XI. Methods where W is the other values and Z is heterocyclyl.
- XII. Methods where W is the other values and Z is non-hetero.

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Via telephone on 8-8-2002 Ms. Shen elected GP. I which is made up of claims 1, 2, 4-12, 14-22 and 27. Non-elected claims 3, 13, 23-26 and 28-35 and the non-elected parts of claims 1, 2, 4-11, 14-17 and 19-21 are withdrawn from consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 8, 9, 12, 16, 19, 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanfilipo et al, J. Med. Chem. 1998, 31, 2221-2227 cited by applicants.

This reference relates to imidazo [1, 2-a] pyridines containing a 4(disubstituted amino alkoxy)-phenyl substituent in the 2-position which have calcium channel blocking and local anesthetic activity. Among the disubstituted amino groups taught are those in which the amino group is part of a ring such as piperidine, morpholine and imidazole.

Applicants claim 1 (while claim 27 doesn't) has a proviso removing most of the piperidino and morpholinopropoxy compounds. See compounds 28 and 29 on p. 2224 in Table II. However the imidazolopropoxy compounds are met by compound 30 in said Table.

The pharmaceutical compositions are anticipated because of the anesthetic utility disclosure of the reference.

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The species named 2-[4-(3-piperidin-1-yl-propoxy)-phenyl] imidazo [1, 2-b] pyridine appears in claim 16 at page 90, line 5 and as the active ingredient in pharmaceutical compositions claim 21 at page 91, line 22.

Very importantly in contradiction to what is provided out in independent claim 1, at page 87, lines 12-14 are claims 16, 18, 21 and 22.

In claim 16 the 3-piperidinopropoxy species contradict the proviso of claim 1. The species of claim 18, the active ingredient species of pharmaceutical composition claim 21 (which is assumed to ultimately depend from claim 1) at page 91, lines 21 and 22 and line 24 and the species of claim 22 also contradict said proviso.

Of course very importantly the last species of claim 16 is the compound specifically made and tested for anesthetic activity (see compound 28) by the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 6, 8, 9, 12, 14, 16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanfilippo et al, supra.

The corresponding lower alkyl and/or lower alkoxy and/or halo substituted and unsubstituted-imidazo [1, 2-a] pyridine compounds are considered obvious since one of ordinary skill in the art would be motivated to make them in view of the teaching of the dibutylamino-propoxyphenyl substituted compounds by the reference. See compounds

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1, 3 4, 5, 20 and 23-35 in Tables I and II. The corresponding cyclic aminobutoxy compounds would be obvious in view of compound 31 of Table II.

Claims 1, 2, 4, 5, 7, 8, 9, 11, 14, 19, 20 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al, cited by applicants.

In this report several 2-[3-or4-(2-piperidin-1-yl^{ethoxy}phenyl) and one 2-[4-(2-pyrrolin-1-yl^{ethoxy}phenyl) imidazo [1, 2-a] pyridines were synthesized and their effect on heme oxygenase activity of plasmodium yoelli and corresponding infected host were studied. See compounds 9, 12, 15 and 16 in Table 1.

Claims 1, 2, 4, 7-9, 11, 14, 19, 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava et al.

Compounds with pyrrolidinethoxy moiety in any position of the phenyl group are considered obvious in view of the reference's teaching of the 3- or 4- position substitution thereof.

Note that one of the 4-(2-piperidinoethoxyphenyl) compounds and the corresponding pyrrolidinoethoxyphenyl compounds also has a methyl group at the 2-position and an isopropyl group at the 5-position. Thus alkyl groups at any position of the phenyl in combination with any position of the cyclic amino group Z is considered obvious.

Claims 1, 2, 4-12, 14-17, 19-21 and 27 are rejected for representing a misjoinder of invention. The non-elected material should be canceled.

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lines 9-11 and claim 27 at p. 96
For example the proviso in claim 1 at page 87, ^{line 7} will be canceled since Z will be limited to heterocyclic (i.e., cyclic). If the proviso in claim 12 is considered for retention it would also have to be modified for the above reasons.

The structure and limits of the compound of formula (I) of claim 19 is unclear.

Claims 1, 2, 4-12 and 14-22 are rejected under 35 U.S.C. 112 for failing to particularly point out the invention. One of the main reasons for the rejection has been explained just above. It is the inclusion of independent species claims of material provisoed out of the independent claim. In a similar vein see the proviso of dependent claim 12 which on its face is contradictory to proviso of claim 1.

Further see the last 2 lines of claim 14 which ^{are} confusing since $NR_{11}R_{12}$ does not have these cyclic values in claim 1 and these values ~~are not~~ fall within Z being a C 2-8 heterocyclic radical, etc.

Further claim 19 is incomplete since there is no formula (I) and the structure is not recited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 308-4544. The examiner can normally be reached on Monday-Friday ^{from} 8 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman can be reached on 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Dentz:mv
August 19, 2002



BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1600